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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,472	09/08/2003	Tracee Eidenschink	S63.2H-11273-US01	2675

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/657,472

Applicant(s)

EIDENSCHINK ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,3,6 and 7 is/are allowed.
- 6) ☒ Claim(s) 4,9 and 13 is/are rejected.
- 7) ☒ Claim(s) 8,10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/3/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 1/31/2007.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 1/12/2007.
2. In the reply, the Applicant amended claims 2, 7-8, 10 and 11.
3. Additionally, the Applicant submitted replacement drawing sheet Fig 5 to obviate the objection to the drawings.
4. The specification was correctly amended to obviate the objection to the specification.
5. Finally, the Applicant filed a terminal disclaimer to co-pending Application 10/747546 that has been approved. Thus, the obvious double patenting rejection to 10/747546 has been obviated.
6. Claims 2, 3, 6-11, 13 and 14 remain pending for examination.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8-11 recite the limitation "any combination thereof". The recitation fails to particularly point out and distinctly claim the agents or cellular material that the applicant regards as the invention. The Applicant has recited a seemingly infinite amount of agents or cellular material by the inclusion of "any combination thereof". The Examiner suggests removing the limitation "any combination thereof".

9. Additionally, claim 8 recites the limitation "other molecules" on ln 13. The Examiner does not know the distinct meaning or metes and bounds of the use of "other molecules"; thus, the claim is rendered indefinite. The Examiner recommends removing the limitation "other molecules" from the claim.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al (6165195) in view of Dayton (5449382).

12. Wilson et al discloses a catheter assembly comprising: a catheter, the catheter comprising a catheter shaft (50), the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough; a rotatable sheath (54), the rotatable sheath extending around an exterior of at least a portion of the catheter shaft and rotatable about the catheter shaft at a position radially outward from the catheter shaft (54, Figs 12G-12I, 16B-D; wherein the Examiner notes that the sheath does extend around at least a portion of the catheter shaft, ie the when inflated the sheath, ie the balloon, extends around the portion of the catheter shaft housing the guidewire lumen; furthermore, the sheath is rotatable about the catheter shaft at a position radially outward, ie when the balloon is inflated, the sheath rotates about when the entire

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catheter shaft is rotated manually, as it reads the limitation does not require the sheath to rotate *separately from or independently from or relative to* the catheter shaft and the Examiner recommends including those claims limitations to the claims), the rotatable sheath having a length substantially less than that of the catheter shaft (Figs 12G-12I, 16B-D); a secondary guide wire housing (55a, 55b), the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough (56b), at least a first distal portion of the guide wire housing in contact with at least a first proximal portion of the rotatable sheath (Figs 12G-12I, 16B-D); and a stent (20), the stent being expandable from a reduced stent state to an expanded stent state, and defining a flow path between a proximal end opening and a distal end opening, the stent being at least partially constructed from a plurality of interconnected stent members that define a plurality of cell openings therebetween (Figs 12G-12I, 16B-D), each of the cell openings being in fluid communication with the flow path, in the reduced stent state the stent is positioned radially outward from and extends around an exterior of at least a portion of the rotatable sheath and at least a portion of the secondary guide wire housing (Figs 12G-12I, 16B-D), a distal end portion of the secondary guide wire housing exiting the flow path of the stent through one of the plurality of cell openings (Figs 12G-12I, 16B-D).

13. However, Wilson et al does not expressly disclose the one therapeutic agent is from the group listed in claim 9. Dayton teaches that it is known to have stents having therapeutic agents (Background and Summary) for the purpose of treating a vessel. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to modify the stent as taught by Wilson et al with the therapeutic agent as taught by Dayton for the purpose of treating a vessel.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 13 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 24 of copending Application No. 10/375689. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same subject matter as follows: the rotatable sheath is disposed about a portion of a catheter shaft, where the rotatable sheath is less than that of the catheter shaft and being rotatably disposed about a portion of a medical balloon or catheter balloon, and where a rotatable collar disposed about a portion of the catheter shaft proximal of the medical balloon.

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Furthermore, the '689 patent is considered to teach or suggest an inflation lumen to one of ordinary skill in the art because the metes and bounds of a catheter balloon and a balloon catheter shaft are well known to include inflation lumens to inflate/deflate the balloon. Secondly, the '689 patent is considered to teach or suggest a rotatable collar (see claim 24). Finally, the '689 patent is considered to teach or suggest a first and second guide wire lumens and housing for the first and second lumens (see claims 1-3; wherein the Examiner notes that the scope of the present application does not preclude the second guide wire lumen from being entirely separate and distinct from the rotatable sheath). The claims in the present application are similar in scope and can be considered merely broader to those of the '689 case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

16. Claims 2-3, 6, 7 are allowed.

17. Claims 8, 10, 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

18. Applicant's arguments filed 1/12/2007 have been fully considered but they are not persuasive.

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19. The Applicant correctly amended independent claim 2 to obviate the 35 USC 102(b) rejection to Wilson et al. However, the Applicant failed to amended independent claim 9 to obviate the 35 USC 103(a) rejection of claim 9 to Wilson et al in view of Dayton (see above). The Examiner suggests amended claim 9 in the same manner as claim 2 was amended to obviate the rejection.

20. The Applicant correctly amended claim 7 to render the claim definite and obviate the 35 USC 112(2nd) paragraph rejection. However, the Applicant failed to amend claims 8-11 to obviate the 35 USC 112(2nd) paragraph rejection pending on those claims (see above). The Examiner suggests amending claims 8-11 in the same manner as claim 7 was amended to obviate the rejection.

21. The Applicant's arguments with respect to the provisional obvious-type double patenting rejections to co-pending applications 10/863724 and 10/757646 are persuasive (see Remarks, pg 12, paragraph 2-3) and the rejections have hereby been withdrawn.

22. The Applicant's arguments with respect to the provisional obvious-type double patenting rejection to co-pending application 10/375689 is persuasive in view of claims 2, 3, and 6 (see Remarks, pg 11, paragraph 12) and the rejection is hereby withdrawn; however, the arguments in view of claims 13-14 are not persuasive (see Remarks, pg 11, paragraph 2) and the rejection is hereby maintained (see discussion above).

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

